APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/844,234	04/27/2001	Gary A. Goetzke	P-9640.00	1436

			EXAMINER
27581	7590	05/03/2006	GLASS, RUSSELL S

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ART UNIT	PAPER NUMBER
3626	

DATE MAILED: 05/03/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

		Application No.	Applicant(s)
		09/844,234	GOETZKE ET AL.
Office Action Summary		Examiner	Art Unit	
		Russell S. Glass	3626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE _3_ MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.
- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on _27 April 2001_.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) _1-26_ is/are pending in the application.

    4a) Of the above claim(s) _27 and 28_ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) _1-26_ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

    Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

    Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

    a)☐ All b)☐ Some * c)☐ None of:

      1.☐ Certified copies of the priority documents have been received.

      2.☐ Certified copies of the priority documents have been received in Application No. _____.

      3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

    * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)

2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
    Paper No(s)/Mail Date _6/1/2001_.

4) ☐ Interview Summary (PTO-413)
    Paper No(s)/Mail Date. _____.

5) ☐ Notice of Informal Patent Application (PTO-152)

6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

During a telephone conversation with John Albricht on 4/21/2006 a provisional

election was made without traverse to prosecute the invention of a method for risk

stratification of potential chronic pain patients in a population, claims 1-26. Applicants

earlier incorrect written election of claims 1-30 was admitted to be non-responsive by

counsel and is hereby withdrawn. Affirmation of this election must be made by

applicant in replying to this Office action. Claims 27 and 28 withdrawn from further

consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected

invention.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created
doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the
unjustified or improper timewise extension of the "right to exclude" granted by a patent
and to prevent possible harassment by multiple assignees. A nonstatutory
obviousness-type double patenting rejection is appropriate where the conflicting claims
are not identical, but at least one examined application claim is not patentably distinct
from the reference claim(s) because the examined application claim is either anticipated
by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140
F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29
USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir.
1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422
F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163
USPQ 644 (CCPA 1969).
A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d)
may be used to overcome an actual or provisional rejection based on a nonstatutory
double patenting ground provided the conflicting application or patent either is shown to
be commonly owned with this application, or claims an invention made as a result of
activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

1.   **Claims 1-26 are provisionally rejected on the ground of nonstatutory double patenting over claims 1-30 of copending Application No. 09/844195.** This is a provisional double patenting rejection since the conflicting claims have not yet been patented.

The subject matter claimed in the instant application is fully disclosed in the referenced copending application and would be covered by any patent granted on that copending application since the referenced copending application and the instant application are claiming common subject matter, as follows: The method for identifying individuals at risk for chronic pain in application number 09/844195 contains substantially the same method steps as the method in the present application for risk stratification of potential chronic pain patients in a population.

Furthermore, there is no apparent reason why applicant would be prevented from presenting claims corresponding to those of the instant application in the other copending application. See *In re Schneller*, 397 F.2d 350, 158 USPQ 210 (CCPA 1968). See also MPEP § 804.

Oath/Declaration

2.   The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because it is not executed by all inventors in accordance with either 37 CFR 1.66 or 1.68.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all

obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3.   **Claims 1-3, 6, 7, 9, 10-14, 16, 17, 19, 20, 23-26 are rejected under 35 U.S.C.**

103(a) as being unpatentable over Hu et al., (U.S. 6,110,109) in view of Comanor et

al., (5,860,917).

4.   As per claim 1, Hu discloses a method for risk stratification of potential chronic

pain patients in a population, comprising:

selecting direct medical indicia that serve as independent variables, (Hu, col. 2,

lines 4-37);

selecting indirect medical indicia that serve as independent variables, (Hu, col. 2,

lines 4-37);

selecting non-medical indicia that serve as independent variables, (Hu, col. 2,

lines 4-37);

selecting an indication that serves as a dependent variable, (Hu, col. 1, lines 43-61);

creating a stratifying model using direct medical indicia, indirect medical indicia, non-medical indicia, and an indication, (Hu, col. 1, lines 43-61); and,

applying the model to a patient to create a patient mathematical expression, (Hu, Fig. 1).

Hu fails to disclose stratifying potential chronic pain patient by comparing each patient mathematical expression to selection objectives. However, such a method is well known in the art as evidenced by Comanor, (Comanor, col. 3, lines 28-32; col. 5, lines 7-11) (disclosing the production of a statistical model for projecting or stratifying a patient response to a treatment regimen, such response being indicative of required medical resources).

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine Comanor with Hu. The motivation would have been to produce robust, statistically significant models that assist clinicians in determining therapies, (Comanor, Abstract).

5.   As per claim 2, Hu discloses a method wherein the model comprises:

a logic structure to define a logical decision process to operate on the independent variables and to progressively reach greater certainty about the patient forecast, (Hu, col. 1, lines 42-61; col. 2, lines 4-37);

weighted variables to reflect greater relevance of certain direct medical indicia, indirect medical indicia, and non-medical indicia to the indication, (Hu, col. 9); and,

equations that represent relationships between or among weighted variables to form an inference engine, (Hu, col. 10).

Hu fails to disclose chronic pain stratifying models. However, such models are well known in the art as evidenced by Comanor, (Comanor, col. 3, lines 28-32; col. 5, lines 7-11) (disclosing the production of a statistical model for projecting or stratifying a patient response to a treatment regimen, such response being indicative of required medical resources).

The motivation to combine Hu and Comanor is as provided in the rejection of claim 1 and incorporated herein by reference.

6.   As per claim 3, Hu discloses a method wherein the chronic pain stratifying inference engine comprises:

dependent variables, independent variables and equations, (Hu, col. 4, lines 11-51).

Hu fails to disclose a minimum number of variables. However, it would have been obvious to one of ordinary skill in the art at the time of the invention to process a large amount of data by including many variables. The motivation would have been to create an accurate model that took into account many variables.

Hu fails to disclose chronic pain stratifying models. However, such models are well known in the art as evidenced by Comanor, (Comanor, col. 3, lines 28-32; col. 5,

lines 7-11) (disclosing the production of a statistical model for projecting or stratifying a

patient response to a treatment regimen, such response being indicative of required

medical resources).

The motivation to combine Hu and Comanor is as provided in the rejection of

claim 1 and incorporated herein by reference.

7.   As per claim 6, Hu discloses a method wherein the weighted variables are

developed using logistical regression to establish relationships between the dependent

variable and independent variables, (Hu, col. 12, lines 7-47).

The motivation to combine Hu and Comanor is as provided in the rejection of

claim 1 and incorporated herein by reference.

8.   As per claim 7, Comanor discloses a method wherein the weighted variables are

developed using discriminate analysis to establish relationships between the dependent

variable and independent variables, (Comanor, col. 10).

The motivation to combine Hu and Comanor is as provided in the rejection of

claim 1 and incorporated herein by reference.

9.   As per claim 9, Hu discloses a method wherein the potential chronic pain patient

risk is identified with a patient mathematical expression generated by the inference

engine operating on the patient indicia and the indication, (Hu, col. 1, lines 42-61).

Hu fails to disclose chronic pain stratification models. However, such models are well known in the art as evidenced by Comanor, (Comanor, col. 3, lines 28-32; col. 5, lines 7-11) (disclosing the production of a statistical model for projecting or stratifying a patient response to a treatment regimen, such response being indicative of required medical resources).

The motivation to combine Hu and Comanor is as provided in the rejection of claim 1 and incorporated herein by reference.

10.   As per claim 10, Hu discloses a method wherein the patient indicia are monitored for changes and the patient mathematical expression is updated when patient indicia change, (Hu, col. 2, lines 38-57).

The motivation to combine Hu and Comanor is as provided in the rejection of claim 1 and incorporated herein by reference.

11.   As per claim 11, Hu discloses a method further comprising:

establishing categorization preferences that specify patient risk characteristics that are desired to be selected, (Hu, col. 2, lines 38-57);

calculating the categorization preferences with each chronic pain patient's mathematical expression to identify relationships between the categorization preferences and each potential chronic pain patient's mathematical expression, (Hu, col. 1, lines 42-61); and,

categorizing each chronic pain patient based upon the relationships between the

categorization preferences and each chronic pain patient's mathematical expression,

(Hu, col. 3, lines 18-56). Hu fails to disclose chronic pain stratifying models. However,

such models are well known in the art as evidenced by Comanor, (Comanor, col. 3,

lines 28-32; col. 5, lines 7-11) (disclosing the production of a statistical model for

projecting or stratifying a patient response to a treatment regimen, such response being

indicative of required medical resources).

The motivation to combine Hu and Comanor is as provided in the rejection of

claim 1 and incorporated herein by reference.

12.   As per claim 12, Comanor discloses a method wherein the selection objectives

are selected from the group consisting of high probability of pain episode, low

probability of pain episode, acute pain, chronic pain, low treatment immediacy, medium

treatment immediacy, high treatment immediacy, high cost, and low cost, (Comanor,

col. 1, lines 46-52) (disclosing selection objectives to determine efficacy such as cost

and physical discomfort).

The motivation to combine Hu and Comanor is as provided in the rejection of

claim 1 and incorporated herein by reference.

13.   As per claim 13, Comanor discloses a method wherein the direct medical indicia

are related to chronic pain in a known medical manner and recorded by a clinician,

(Comanor, col. 15, lines 58-62).

The motivation to combine Hu and Comanor is as provided in the rejection of claim 1 and incorporated herein by reference.

14.   As per claim 14, Comanor discloses a method wherein the direct medical indicia are independent variables selected from the group consisting of primary diagnosis, associated secondary diagnosis, co-morbidities, drug treatment regimen, telephone consultations with a clinician, trauma episodes, palliative care, rehabilitative care, clinician office visits, emergency room visits, and hospitalizations, (Comanor, col. 5, lines 20-37)(disclosing office visits).

The motivation to combine Hu and Comanor is as provided in the rejection of claim 1 and incorporated herein by reference.

15.   As per claim 16, Comanor discloses a method wherein indirect medical indicia are a chronic pain co-morbidity that is recorded by a clinician, (Comanor, col. 1; col. 3, lines 28-32; col. 5, lines 7-11; col. 15, lines 58-62).

The motivation to combine Hu and Comanor is as provided in the rejection of claim 1 and incorporated herein by reference.

16.   As per claim 17, Hu discloses a method wherein the indirect medical indicia are independent variables selected from the group consisting of mental health condition, acute respiratory episodes, diabetes, and heart failure, (Hu, col. 1 and 2)(disclosing heart disease).

The motivation to combine Hu and Comanor is as provided in the rejection of claim 1 and incorporated herein by reference.

29.   As per claim 19, Hu discloses a method wherein the non-medical indicia are independent variables selected from the group consisting of alcohol consumption, smoking status, weight gain, pain perception factors, life satisfaction measures, patient support structure, day-time distractions, marital relationship quality, personality profile, courtroom demeanor, reputation for truth and veracity, demeanor of associates, reputation of counsel, familial persuasion, financial needs, financial expectations, legal experience, personal injury history, family and friends injury history, cognitive ability, emotional maturity, and media reporting related to the indication, (Hu, col. 1) (disclosing various disease prediction factors, based upon lifestyle choices such as smoking and drinking, to adjust categorization).

The motivation to combine Hu and Comanor is as provided in the rejection of claim 1 and incorporated herein by reference.

17.   As per claim 20, Hu discloses a method wherein the sources for non-medical indicia are selected from the group consisting of medical records, patient surveys, patient self-reports, employer databases, workers' compensation records, medical chart reviews, patient interviews, treating clinician interviews, and family member interviews, (Hu, col. 10, lines 40-46)(disclosing patent surveys).

The motivation to combine Hu and Comanor is as provided in the rejection of claim 1 and incorporated herein by reference.

18.   As per claim 23, Hu discloses a method wherein the patient population is

selected from the group consisting of payer database, employer database, clinician

database, and workers' compensation database, (Hu, col. 2, lines 38-57)(disclosing

selecting patients from a clinician database).

The motivation to combine Hu and Comanor is as provided in the rejection of

claim 1 and incorporated herein by reference.

19.   As per claim 24, Hu discloses a method for risk stratification of potential chronic

pain patients, comprising:

accessing a chronic pain risk model having direct medical indicia, indirect

medical indicia, non-medical indicia, and a chronic pain indication that are arranged

logic structure, with weighted variables, and equations representing relationship

between or among the variables, (Hu, col. 1, lines 42-61; col. 2, lines 4-20; col. 9);

applying the chronic pain risk model to a potential chronic pain patients to create

a patient mathematical expression for each potential chronic pain patient, (Hu, fig. 1;

col. 1, lines 13-28);

identifying potential chronic pain patient risk by comparing each patient

mathematical expression to selection objectives, (Hu, col. 1, lines 42-61);

establishing categorization preferences that specify characteristics of patients

that are desired to be categorized, (Hu, col. 2, lines 38-57);

calculating the categorization preferences with each chronic pain patient's

mathematical expression to identify relationships between the categorization

preferences and each potential chronic pain patient's mathematical expression, (Hu, col.

1, lines 42-61);

categorizing each potential chronic pain patient based upon the relationships

between the categorization preferences and each chronic pain patient's mathematical

expression, (Hu, col. 3, lines 18-56); and,

monitoring the chronic pain patient's direct medical indicia, indirect medical

indicia, and non-medical indicia for changes and updating the patient's mathematical

expression based upon changes to the potential chronic pain patient's direct medical

indicia, indirect medical indicia, and non-medical indicia, (Hu, col. 2, lines 38-57).

Hu fails to disclose chronic pain stratifying models. However, such models are

well known in the art as evidenced by Comanor, (Comanor, col. 3, lines 28-32; col. 5,

lines 7-11) (disclosing the production of a statistical model for projecting or stratifying a

patient response to a treatment regimen, such response being indicative of required

medical resources).

The motivation to combine Hu and Comanor is as provided in the rejection of

claim 1 and incorporated herein by reference.

20.   As per claims 25 and 26, Hu discloses a computer software product that includes

a medium readable by a computer, the medium having stored thereon instructions for

stratifying chronic pain patient medical resources, comprising:

a first set of instructions when executed by the computer, causes the computer

access a chronic pain stratifying model having direct medical indicia, indirect medical

indicia, non-medical indicia, and a chronic pain indication that are arranged logic

structure, with weighted variables, and equations representing relationship between or

among the variables, (Hu, col. 1, lines 42-61; col. 2, lines 4-20; col. 9);

a second set of instructions when executed by the computer, causes the

computer to applying the chronic pain stratifying model to a chronic pain patient to

create a patient mathematical expression, (Hu, fig. 1; col. 1, lines 13-28); and,

a third set of instructions when executed by the computer, cause the computer to

forecast chronic pain patient medical resources comparing each patient mathematical

expression to selection objectives, (Hu, col. 1, lines 42-61); and,

a fourth set of instruction when executed by the computer, cause the computer to

establish categorization preferences that specify characteristic of a forecast that are

desired to be categorized, (Hu, col. 2, lines 38-57);

a fifth set of instruction when executed by the computer, cause the computer to

calculate the categorization preferences with each chronic pain patient's mathematical

expression to identify relationships between the categorization preferences and each

chronic pain patient's mathematical expression, (Hu, col. 1, lines 42-61); and,

a sixth set of instruction when executed by the computer, cause the computer to

categorize the forecast based upon the relationships between the categorization

preferences and each chronic pain patient's mathematical expression, (Hu, col. 3, lines

18-56).

Hu fails to disclose chronic pain stratifying models. However, such models are

well known in the art as evidenced by Comanor, (Comanor, col. 3, lines 28-32; col. 5,

lines 7-11) (disclosing the production of a statistical model for projecting or stratifying a

patient response to a treatment regimen, such response being indicative of required

medical resources).

The motivation to combine Hu and Comanor is as provided in the rejection of

claim 1 and incorporated herein by reference.

21.   **Claims 4, 5 rejected under 35 U.S.C. 103(a) as being unpatentable over Hu
et al., (U.S. 6,110,109) in view of Comanor et al., (5,860,917) and further in view of
Goldman et al., (U.S. 2001/0054032).**

22.   As per claims 4 and 5, the collective system of Hu and Comanor fails to disclose

a method wherein the logic structure is developed using Chi-Square Automatic

Interaction Detection (CHAID) analysis or Classification Adjusted Regression Tree

(CART) analysis to establish relationships between a dependent variable and

independent variables.

However, using CHAID and CART to establish relationships between a

dependent variable and independent variables is well known in the art as evidenced by

Goldman, (Goldman, (U.S. 2001/0054032).

It would have been obvious to one of ordinary skill in the art to combine Goldman

with the collective system of Hu and Comanor. The motivation would have bee to use a

known statistical mechanism to determine correlations among data, (Goldman, ¶ 118).

23.   **Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hu et al., (U.S. 6,110,109) in view of Comanor et al., (5,860,917) and further in view of Blum et al., (U.S. 5,500,343).**

24.   As per claim 8, The collective system of Hu and Comanor fails to disclose a method wherein appropriateness of patient indicia is evaluated using the Hosmer-Lemeshow Goodness of Fit Analysis. However, such a method is well-known in the art as evidenced by Blum, (Blum, col. 57, lines 31-42).

It would have been obvious to one of ordinary skill in the art to add Blum to the collective system of Hu and Comanor. The motivation would have been to determine whether the model fits the data, (Blum, col. 57, lines 31-42).

The motivation to combine Hu and Comanor is as provided in the rejection of claim 1 and incorporated herein by reference.

25.   **Claims 15, 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hu et al., (U.S. 6,110,109) in view of Comanor et al., (5,860,917) and further in view of Wong et al., (U.S. 5,976,082).**

27.   As per claim 15, the collective system of Hu and Comanor fails to disclose a method wherein the sources for direct medical indicia are selected from the group consisting of claims records, medical records, workers' compensation records, and

employer records. However, such a method is well known in the art as evidenced by

Wong, (Wong, col. 3, lines 49-60).

The motivation to combine Hu and Comanor is as provided in the rejection of

claim 1 and incorporated herein by reference.

28.   As per claim 18, the collective system of Hu and Comanor fails to disclose a

method wherein the sources for indirect medical indicia are selected from the group

consisting of claims records, medical records, workers' compensation records, and

employer records. However, such a method is well known in the art as evidenced by

Wong, (Wong, col. 3, lines 49-60).

The motivation to combine Hu and Comanor is as provided in the rejection of

claim 1 and incorporated herein by reference.

32.   **Claims 21, 22 are rejected under 35 U.S.C. 103(a) as being unpatentable**

over Hu et al., (U.S. 6,110,109) in view of Comanor et al., (5,860,917) and further in

view of Grouhel et al., (U.S. 6,353,024).

33.   As per claim 21 and 22, the collective system of Hu and Comanor fails to

disclose a method wherein the chronic pain indication is selected from the group

consisting of Peripheral Neuropathy; Stump Pain; Phantom Pain; Complex Regional

Pain Syndrome Type I (Reflex Sympathetic Dystrophy); Complex Regional Pain

Syndrome Type II (Causalgia); Central Pain; Rheumatoid Arthritis; Osteoarthritis; Sickle

Cell Arthropathy; Stiff Man Syndrome; Osteoporosis; Guillain-Barre Syndrome; Superior

Pulmonary Sulcus Syndrome (Pancoast Tumor); Pain of Skeletal Metastatic Disease of

the Neck, Arm, or Shoulder Girdle; Carcinoma of Thyroid; Post Herpetic Neuralgia;

Syphilis (Tabes Dorsalis and Hypertrophic Pachymeningitis); Primary Tumor of a

Vertebral Body; Radicular Pain Attributable to a Prolapsed Cervical Disk; Traumatic

Avulsion of Nerve Roots; Primary Tumor of a Vertegral Body; Radicular Pain

Attributable to a Thoracic Disk; Chemical Irritation of the Brachial Plexus; Traumatic

Avulsion of the Brachial Plexus; Postradiation Pain of the Brachial Plexus; Painful Arms

and Moving Fingers; Brachial Neuritis (Brachial Neuropathy, Neuralgic Amyotrophy,

Parsonage-Turner Syndrome); Raynaud's Disease; Raynaud's Phenomenon; Frostbite

and Cold Injury; Brythema Pernio (Chilblains); Acrocyanosis; Livedo Reticularis;

Volkmann's Ischemic Contracture; Thromboangiitis; Intermittent Claudication; Rest

Pain; Gangrene Due to Arterial Insufficiency; Other Postinfectious and Segmental

Peripheral Neuralgia; Angina Pectoris; Postmastectomy Pain Syndrome (Chronic

Nonmalignant); Late Postmastectomy Pain or Regional Carcinoma; Segmental or

Intercostal Neuralgia; Chronic Pelvic Pain Without Obvious Pathology; Pain from

Urinary Tract; Carcinoma of the Bladder; Lumbar Spinal or Radicular Pain after Failed

Spinal Surgery; Spinal Stenosis (Cauda Equina Lesion); Pain referred from Abdominal

or Pelvic Viscera or Vessels Perceived as Sacral Spinal Pain; Femoral Neuralgia; and,

Sciatica Neuralgia, and wherein the source for chronic pain indications is the

International Association for the Study of Pain (IASP) chronic pain guidelines

However, such a method is well known in the art as evidenced by Grouhel,

(Grouhel, col. 4, line 59-col. 5, line 25)(disclosing osteoarthritis and IASP).

It would have been obvious to one of ordinary skill in the art to add Grouhel to the

collective system of Hu and Comanor. The motivation would have been to have a

comprehensive list of chronic pain conditions and to identify those conditions where

pain persists beyond the normal healing time, (Grouhel, col. 5, lines 1-8).

The motivation to combine Hu and Comanor is as provided in the rejection of

claim 1 and incorporated herein by reference.

Conclusion

34.   The prior art made of record and not relied upon is considered pertinent to

applicant's disclosure is as follows: Lash, (U.S. 2001/0020229); Simpson, (U.S.

6,266,645); McCartney, (U.S. 5,778,345).

Any inquiry concerning this communication or earlier communications from the

examiner should be directed to Russell S. Glass whose telephone number is 571-272-

3132. The examiner can normally be reached on M-F 8-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's

supervisor, Joseph Thomas can be reached on 571-272-6776. The fax phone number

for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the

Patent Application Information Retrieval (PAIR) system. Status information for

published applications may be obtained from either Private PAIR or Public PAIR.

Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see http://pair-direct.uspto.gov. Should

you have questions on access to the Private PAIR system, contact the Electronic

Business Center (EBC) at 866-217-9197 (toll-free).

RSG
4/20/2006

C. LUKE GILLIGAN
PATENT EXAMINER